UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/649,077	08/27/2003	Birinder R. Boveja		4660

43987 7590 04/04/2006

BIRINDER R. BOVEJA & ANGELY WIDHANY
P. O. BOX 210095
MILWAUKEE, WI 53221

EXAMINER	
BERTRAM, ERIC D	
ART UNIT	**PAPER NUMBER**
3766	

DATE MAILED: 04/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/649,077	BOVEJA ET AL.	
	Examiner	Art Unit	
	Eric D. Bertram	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 March 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-37 and 47-57* is/are pending in the application.

4a) Of the above claim(s) *25-37 and 49-57* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-24,47 and 48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *27 August 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *8/27/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of claims 1-24, 47 and 48 in the reply filed on 3/22/2006 is acknowledged. The traversal is on the ground(s) that since all the pending claims have been categorized in the same class, searching and examining all of the claims would not impose a serious burden on the Examiner. This is not found persuasive because despite their common class, the groups are classified in different subclasses, and as such would NOT be covered in a single field of search.

The requirement is still deemed proper and is therefore made FINAL.

2. Newly submitted claim 49-57 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the new claims are included in the non-elected invention in that they are directed to a system capable of use on tissue other than the vagus nerve, as originally described in the restriction requirement from 2/22/05.

Accordingly, claims 49-57 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Information Disclosure Statement

3. The information disclosure statement (IDS) submitted on 8/27/2003 was filed in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Objections

4. Claim 1 is objected to because of the following informalities: in line 2 of the claim, --and-- should be inserted between "obesity" and "eating". Also, in line 5 of the claim, Examiner recommends inserting --comprises-- in place of "comprising." Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-24, 47 and 48 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: providing or applying electrical pulses to one or both vagus nerves. This step is critical because no stimulation is being positively performed on the nerves to perform "a method to provide electrical pulses to one or both nerves", "a method or providing pulsed electrical stimulation to one or both vagus nerve(s)", and a "method of providing electrical pulses to one or both vagus nerve(s)," as stated in the claims.

7. Claims 3-24, 47 and 48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. In claims 3-7, "electrical pulses are applied" is vague as method steps must be in the active voice. It is unclear if the step of applying electrical pulses is being positively recited. It is suggested to say "applying said electrical pulses."

9. Claims 8, 14, 16, 18 and 24 are vague because they are not further limiting the method since they do not contain any method steps.

10. In claims 9, 10, 19 and 20, the phrase "said implanted stimulator is programmed" should be in the active voice, such as "further comprising programming said implanted stimulator."

11. In claims 11 and 21, the phrase "stimulator is wirelessly networked" should be in the active voice.

12. In claims 12 and 22, the phrase "communications is used" should be in the active voice.

13. In claims 12, 16 and 22, the phrase "and the like" renders the claim(s) indefinite because the claim(s) include(s) elements not actually disclosed (those encompassed by "and the like"), thereby rendering the scope of the claim(s) unascertainable. See MPEP § 2173.05(d).

14. In claims 13 and 23, the phrase "remotely control said electrical pulses" should be in the active voice.

15. In claim 15, the phrase "electrical stimulation is provided" should be in the active voice.

16. In claim 17, the phrase "stimulator is utilized" should be in the active voice.

17. In claim 47, the phrase "electric pulses neuromodulate" should be in the active voice.

18. In claim 48, the phrase "pulses are provided" should be in the active voice.

Claim Rejections - 35 USC § 102

19. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

20. Claims 1, 2, 4, 8, 9, 11-13, 15-19, 21-23, 47 and 48 are rejected under 35 U.S.C. 102(b) as being anticipated by Adkins et al. (US 5,928,272, hereinafter Adkins). Adkins discloses a method for stimulating and neuromodulating the vagus nerve of a patient in order to provide treatment for neurological disorders (see abstract). Adkins provides an implanted stimulator 10 with an implanted pulse generator module 33 an implanted stimulus receiver module 40. Adkins further provides an external stimulator 18 that is inductively coupled to the implanted stimulus receiver 40, as shown by the inductor symbol 40 in figure 2. The external stimulator 18 is thus wirelessly networked for bi-directional communications with the implanted stimulator in order to manage and optimize the patient's therapy, specifically the pulse parameters, including current, pulse frequency, pulse width, amplitude and on-off timing (Col. 2, lines 35-40 and 52-60). Adkins also provides an implanted lead 16 in electrical contact with the implanted stimulator, as well as an electrode array 15 in contact with the vagus nerve above a

diaphragmatic level, as shown in figure 1 (Co. 1, lines 55-60). The implanted stimulator further comprises controlling means in the form of microprocessor 36 that controls both the implanted pulse generator and the implanted stimulus receiver (Col. 2, line 35).

Claim Rejections - 35 USC § 103

21. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

22. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

23. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

24. Claims 3 and 5-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adkins in view of Barrett et al. (US 2002/0087192, hereinafter Barrett). Adkins, as described above, discloses the applicant's basic invention with the exception of stimulating both the left and right vagus nerves at a level below the diaphragm of a patient. Attention is directed to the secondary reference of Barrett, that discloses stimulating the left and right vagus nerves, using one or two stimulators, in order to treat obesity (see abstract and figures 1 and 2). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to modify the system of Adkins to stimulate both the left and right vagus nerves below the diaphragm since this is a known method that may be more easily accomplished than stimulation above the diaphragm (para. 0015).

25. Claims 10, 14, 20 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adkins in view of Mann et al. (US 2002/0055761, hereinafter Mann). Adkins, as described above, discloses the applicant's basic invention with the exception of programming the implanted stimulator with a magnet. Attention is directed to the secondary reference of Mann, that discloses the use of a magnet in an external programmer 20, used to program an implanted stimulator 10. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to modify the system of Adkins by adding a magnet as a programmer since this is an old and well known method, as taught by Mann.

26. Regarding claims 14 and 24, Adkins, as described above, discloses the applicant's basic invention with the exception of using a rechargeable battery in the implanted stimulator capable of being recharged by an external power source. Attention is directed to the secondary reference of Mann, that discloses the use of an external power source 92 use to recharge a battery 15 that is in implanted stimulator 100. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to modify the system of Adkins by adding an external power source to recharge a battery since this allows the power to be replenished without removing the implanted stimulator from the patient.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric D. Bertram whose telephone number is 571-272-3446. The examiner can normally be reached on Monday-Thursday and every other Friday from 9-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on 571-272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert E. Pezzuto
Supervisory Patent Examiner
Art Unit 3766

Eric D. Bertram
Examiner
Art Unit 3766

EDB